UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P O Box 1450
Alexandria, Virginia 22313-1450
www uspto gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,436	09/06/2005	Silvio Aime	57708/380	7608

35743 7590 11/18/2008
KRAMER LEVIN NAFTALIS & FRANKEL LLP
INTELLECTUAL PROPERTY DEPARTMENT
1177 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER	
SCHLIENTZ, LEAH H	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
11/18/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

klpatent@kramerlevin.com

Office Action Summary	Application No.	Applicant(s)	
	10/522,436	AIME ET AL.	
	Examiner	Art Unit	
	Leah Schlientz	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 27 August 2008.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) 14 and 15 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-13 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/27/08 has been entered.

Status of Claims

Claims 1-15 are pending, of which claims 14 and 15 are withdrawn from consideration at this time as being drawn to a non-elected invention. Claim 1 has been amended. Claims 1-13 are readable upon the elected invention and are examined herein on the merits for patentability.

Response to Arguments

Any rejections not reiterated herein have been withdrawn as being overcome by amendment. Response to Applicant's arguments is incorporated into new grounds for rejection.

New Grounds for Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 4 – 7 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klaveness *et al.* (US 4,985,233), as evidenced by Encylopedia Britannica Article, "Reticuloendothelial System," in view of Ranney (US 5,155,215).

Klaveness discloses methods of diagnosis comprising administering to a human body or to a selected region thereof a contrast effective amount of a diagnostic agent comprising a physiologically tolerable, water insoluble, water-swellable, hydroxyl group containing, particulate macromolecular product which is cross-linked to form a three-dimensional network and carries within cavities therein at least one non-radioactive paramagnetic metal species, said product comprising at least one water-insoluble material selected from the group consisting of polysaccharides, polymerized sugar

alcohols and derivatives thereof; and generating an NMR or ultrasound image of said region (see claim 1). The paramagnetic metal may be gadolinium or manganese (claim 7). Suitable materials which may be crosslinked to water-insoluble but water-swellable gel particles include dextran (column 4, lines 49 – 54). As an alternative to the paramagnetic species being present within cavities within the macromolecular product (i.e. non-covalently bound), the paramagnetic species can be chemically bound in the macromolecular product via a chelate complex (column 6, lines 1 – 25). Such chelate-forming groups (such as DTPA, EDTA, etc.) are covalently bound to the hydroxyl groups of the polymeric polymerized carbohydrate via a carboxylic acid such as to produce an ester bond to the macromolecular product (column 6, lines 65 - column 7, line 17). When particles consisting of such macromolecular products are degraded in the body, smaller water-soluble fragments are formed. For example, degradable particles may be taken up by the reticuloendothelial system (RES) of e.g. the liver after parenteral administration for investigation of the liver (column 2, lines 35 – 50).

The Encylopedia Britannica article entitled “Reticuloendothelial System” is included to demonstrate that Klaveness’s teaching that the degradable particles are taken up by the reticuloendothelial system for liver investigation inherently meets the limitation that the particles are internalized by cells, as claimed, because the article teaches that the reticuloendothelial system is a class of phagocytic cells that take up particular substances.

Therefore Klaveness meets the instant claim limitations of a) exposing insoluble particles comprising a gadolinium chelate bound to a macromolecular component and b) internalizing the particles inside the cells (i.e. via entrapment by the endothelial system). Upon introduction into the cells, the particles would inherently be exposed to enzymes or effectors in the environment to thereby degrade the particles, as Klaveness also teaches that the particles are degradable, but does not specifically recite that MRI is achieved via T1-weighted sequences.

Ranney discloses that T1 and T2 times have reciprocal effects on image intensity. Intensity is increased by either shortening the T1 or lengthening the T2. Tissue contrast occurs naturally and is related to variations in the chemical environments around water protons (major contributor) and lipid protons (usually minor). Chemical agents have been used to enhance this natural contrast. The one most widely tested clinically is the paramagnetic metal ion, gadolinium. Although gadolinium shortens both the T1 and T2 times, at the low dose used for clinical imaging, the T1 effect generally predominates and the image becomes brighter. Also, the rf pulse sequence can be programmed to accentuate T1 changes and diminish those due to T2. Hence, "T1-weighted" enhancement can be achieved by selecting the most favorable Gd dose and pulse sequence (column 2, lines 25-45).

It would have been obvious to one of ordinary skill in the art at the time of the invention to perform the MRI diagnosis disclosed by Klaveness via T1 weighted sequences because Ranney teaches that such sequences lead to image enhancement in conjunction with gadolinium contrast agents.

Applicant argues on pages 5-9 of the Response that Klaveness merely describes a method of diagnosis comprising administering a water-insoluble, water-swellable, hydroxyl-group-containing particulate macromolecular product which is cross-linked to form a three-dimensional network, and which carries within its cavities at least one non-radioactive paramagnetic metal species and which generates an NMR or ultrasound image of said region and that Klaveness fails to disclose a method of cellular labeling.

This is not persuasive, MRI is at least a method of "labeling" cells which are imaged.

Applicants further argues that Klaveness' particles provide MRI imaging independently of their degradation. In fact, for example, insoluble particles which are not degradable in the body may be used for investigation of body cavities (column 5, lines 1214). Thus, in the method of Klaveness, degradation of the insoluble particles is not mandatory for obtaining water-soluble positive MRI-imaging probes (i.e. for recording MRI images of a concerned cell), but is only a way to reduce the size of the insoluble macromolecules and to form better excretable fragments.

This is not found to be persuasive. Klaveness even though degradation is not necessarily mandatory, degradation is clearly taught, and thereby addresses applicant's claims. For example, Klaveness teaches that smaller water-soluble fragments are formed. For example, degradable particles may be taken up by the reticuloendothelial system (RES) of e.g. the liver after parenteral administration for investigation of the liver (column 2, lines 35 – 50).

Applicant argues that the Britannica article fails to show that the Klaveness particles would be inherently exposed to enzymes or effectors in the environment to form water-soluble MR-imaging probes.

This is not found to be persuasive. Applicant's claims are very broad, and "other effectors in the environment" is addressed because Klaveness teaches degradation of the particles into water soluble fragments.

Applicant further argues that Klaveness tails to disclose a method of cellular labeling comprising first internalizing the insoluble particles inside the cells and then degrading the insoluble particles by enzymes or by effectors to form water-soluble positive MR- imaging probes, rather it that degradation occurs outside RES cells, i.e. before RES cell internalization.

This is not found to be persuasive. At least some further degradation would occur within RES cells, whose function is to engulf and destroy for excretion, as cited by Applicant above. Such destruction would result in further degradation. Imaging of liver (e.g. while contrast agent is present in RES cells) meets the claims.

Claims 1, 4, 6 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shikata *et al.* (*Eur. J. Pharmaceutics and Biopharmaceutics*, 2002, 53, p. 57 – 63), in view of Ranney (US 5,155,215).

Claims 1 and 4, 6 and 8 – 10 are rejected under 35 U.S.C. 102(a) as being anticipated by Shikata discloses the accumulation of gadolinium loaded as gadopentetic acid (Gd-DTPA) in chitosan nanoparticles (Gd-nanoCPs) which was evaluated in vitro in

cultured cells (abstract). The Gd-nanoCPs were designed for gadolinium capture therapy for cancer, which can be integrated with MRI diagnosis (page 57, left column). Shikata meets the instant claim limitations of a) exposing insoluble particles comprising a gadolinium chelate entrapped in a chitosan network to cells and b) internalizing the particles inside the cells. Upon introduction into the cells, the particles would inherently be exposed to enzymes or effectors in the environment to thereby degrade the particles, as Shikata also teaches that chitosan is biodegradable (bioerodible) (page 57, right column).

Shikata does not specifically recite that MRI is achieved via T1-weighted sequences.

Ranney discloses that T1 and T2 times have reciprocal effects on image intensity. Intensity is increased by either shortening the T1 or lengthening the T2. Tissue contrast occurs naturally and is related to variations in the chemical environments around water protons (major contributor) and lipid protons (usually minor). Chemical agents have been used to enhance this natural contrast. The one most widely tested clinically is the paramagnetic metal ion, gadolinium. Although gadolinium shortens both the T1 and T2 times, at the low dose used for clinical imaging, the T1 effect generally predominates and the image becomes brighter. Also, the rf pulse sequence can be programmed to accentuate T1 changes and diminish those due to T2. Hence, "T1-weighted" enhancement can be achieved by selecting the most favorable Gd dose and pulse sequence (column 2, lines 25-45).

It would have been obvious to one of ordinary skill in the art at the time of the invention to perform the MRI diagnosis disclosed by Shikata via T1 weighted sequences because Ranney teaches that such sequences lead to image enhancement in conjunction with gadolinium contrast agents.

Applicant argues on pages 9-11 of the Reponse that Shikata fails to disclose the degradation of insoluble particles by enzymes or other effectors in the surrounding environment to form water-soluble positive MR imaging probes, instead Shikata's insoluble Gd-nanoCPs nanopaticles, once internalized inside targeted tumor cells, provide desired therapeutic effect, i.e. without requiring degradation, in the surrounding environment so as to form water soluble MR imaging probes. Applicant argues that the adjective "biodegradable" or "bioerodible" does not define particles "able to form a water-soluble positive MR imaging probe, allowing MR image registration", but merely characterizes a compound that may be destroyed or degraded inside the body by suitable effectors.

This is not persuasive. Shikata teaches particles having the same structural elements as those claimed, therefore they must be capable of the same functional properties, whether or not such properties are recited by the reference. A composition and its properties are inseparable.

Applicant further argues that Shikata fails to disclose how to make an MRI diagnosis and does not teach a method of cellular labeling comprising recording MRI images of targeted cells by use of T1-weighted sequences.

This is not found persuasive. Use of T1-weighted sequences is common and obvious in MRI diagnosis, as shown by Ranney.

Claims 1 - 3 and 6 are rejected under 35 U.S.C. 102(a) as being anticipated by Kabalka *et al.* (*Mag. Res. in Medicine*, 1988, 8, 53, p. 89 – 95), as evidenced by Encylopedia Britannica Article, "Reticuloendothelial System," in view of Ranney (US 5,155,215).

Kabalka discloses gadolinium-labeled liposomes as paramagnetic contrast agents. An amphipathic derivative of the chelating ligand diethylenetriaminepentaacetic acid is prepared (i.e. DTPA-SE), by conjugation of stearyl alcohol to DTPA via an ester bond (see Figure 1, page 90). Liposomes were formed mixing Gd-DTPA, egg phosphatidylcholine, and cholesterol, and were then dried, vacuum desiccated and resuspended in phosphate buffered saline. The suspensions were sonicated to produce the desired small unilamellar vessicles with an average diameter of 0.05 micrometer (page 91). The liposomes can be used to deliver antibiotics, chemotherapeutic agents, or Gd-DTPA to the liver because they are rapidly entrapped by the endothelial system and concentrate in normal liver (page 89 and 92). The liposomes containing paramagnetic amphiphilic agents significantly enhance the MR signal intensity in T1-weighted MRI, and appear to be suitable contrast agents for enhancement of organs such as the liver, spleen, bone marrow, and other organs rich in macrophage (i.e. phagocytotic cells) activity.

In the instant case, the Encylopedia Britannica article entitled "Reticuloendothelial System" is included to demonstrate that Kabalka's teaching that the liposomes are taken up by the reticuloendothelial system inherently meets the limitation that the particles are internalized by cells, as claimed, because the article teaches that the reticuloendothelial system is a class of phagocytic cells that take up particular substances.

Therefore, Kabalka meets the instant claim limitations of a) exposing insoluble particles comprising a gadolinium chelate having an aliphatic chain conjugated thereto and b) internalizing the particles inside the cells (i.e. via entrapment by the endothelial system). Upon introduction into the cells, the particles would inherently be exposed to enzymes or effectors in the environment to thereby degrade the particles, as Kabalka also teaches that the gadolinium-labeled liposomes containing the diester reagent are cleared from the liver rapidly as a consequence of the labile nature of the ester linkages in the acidic environment of the liver (page 94).

Kabalka does not specifically recite that MRI is achieved via T1-weighted sequences.

Ranney discloses that T1 and T2 times have reciprocal effects on image intensity. Intensity is increased by either shortening the T1 or lengthening the T2. Tissue contrast occurs naturally and is related to variations in the chemical environments around water protons (major contributor) and lipid protons (usually minor). Chemical agents have been used to enhance this natural contrast. The one most widely tested clinically is the paramagnetic metal ion, gadolinium. Although

gadolinium shortens both the T1 and T2 times, at the low dose used for clinical imaging, the T1 effect generally predominates and the image becomes brighter. Also, the rf pulse sequence can be programmed to accentuate T1 changes and diminish those due to T2. Hence, "T1-weighted" enhancement can be achieved by selecting the most favorable Gd dose and pulse sequence (column 2, lines 25-45).

It would have been obvious to one of ordinary skill in the art at the time of the invention to perform the MRI diagnosis disclosed by Kabalka via T1 weighted sequences because Ranney teaches that such sequences lead to image enhancement in conjunction with gadolinium contrast agents.

Applicant argues on pages 11-13 of the Response that Kabalka fails to disclose degradation of insoluble particles by enzymes or effectors in the environment to form water-soluble MR-imaging probes, and that instead Kabalka describes that liposomes are so insoluble that they remain in the liver indefinitely, especially those which contain Gd-DTPA-SA (page 94).

This is not persuasive. Kabalka teaches at least some degradation (e.g. 50% for Gd-DTPA-SE) having ester linkages are labile and produce the degradation product Gd-DTPA (page 94). Applicant claims ester linkages, thereofre Kabalka meets the claims.

Applicant further argues that Kabalka fails to teach cellular labeling, instead teaches paramagnetic liposomal agents for use as MRI contrast agents, especially of the liver.

This is not found to be persuasive. MRI is at least a method of "labeling" cells which have taken up the contrast agent (e.g. RES cells in liver, for example).

Claims 1, 2 and 4 – 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klaveness *et al.* (US 4,985,233), in view of Grinstaff *et al.* (US 5,498,421), further in view of Ranney (US 5,155,215).

Klaveness teaches degradable water-insoluble macromolecular particles containing a paramagnetic species and methods of use thereof, as set forth above

Klaveness does not specifically teach a targeting moiety on the particles, and does not teach that chitosan is the polysaccharide which is employed.

Grinstaff teaches compositions useful for the in vivo delivery of biologic which is associated with a polymeric shell formulated from a biocompatible material (abstract). Suitable biologics to be encompassed within the shell include paramagntic cations such as Gd, Mn, etc. (column 7, lines 10 – 15 or column 14, line 32). The polymeric shells can be administered intravenously, making imaging of vascularized organs possible. Organ specificity is achieved as a result of uptake of micron-sized organofluorine-containing polymeric shells by the reticuloendothelial system (RES). In addition, lymph nodes within the lymphatic circulation contain cells of the RES (column 6, lines 58+). The polymeric shells containing solid, liquid of gas cores of biologic allows for delivery, and the walls of the polymeric shell are generally completely degradable in vivo by proteolytic enzymes (column 15, line 15 – 23). Suitable polymeric shells include

polysaccharides (e.g. cellulose, dextrans, alginates, chitosan, and the like) (column 8, lines 49 – 51). Other functional proteins, such as antibodies, which facilitate targeting of a biologic to a desired site can also be used in the formulation of the polymeric shell (column 9, lines 10 – 13).

Ranney discloses that T1 and T2 times have reciprocal effects on image intensity. Intensity is increased by either shortening the T1 or lengthening the T2. Tissue contrast occurs naturally and is related to variations in the chemical environments around water protons (major contributor) and lipid protons (usually minor). Chemical agents have been used to enhance this natural contrast. The one most widely tested clinically is the paramagnetic metal ion, gadolinium. Although gadolinium shortens both the T1 and T2 times, at the low dose used for clinical imaging, the T1 effect generally predominates and the image becomes brighter. Also, the rf pulse sequence can be programmed to accentuate T1 changes and diminish those due to T2. Hence, "T1-weighted" enhancement can be achieved by selecting the most favorable Gd dose and pulse sequence (column 2, lines 25-45).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to include a targeting moiety on the particles disclosed by Klaveness because it is well-known in the art to include such substances on similar polymeric particles for the purposes of site-directed imaging or delivery, as taught by Grinstaff. One would have been motivated to do so, and would have had a reasonable expectation of success in doing so because such targeting moieties offer benefits such as site-specific imaging. It would have been further obvious to substitute chitosan as a

functionally equivalent saccharide polymer to those employed by Klaveness, and one would have had a reasonable expectation of success in doing so, because Grinstaff teaches that chitosan is analogous to those employed by Klaveness for preparing polymeric particles. Both Klaveness teach and Grinstaff teach degradable polymeric particles having paramagnetic species encompassed therein which may be taken up by the reticuloendothelial system (RES) of e.g. the liver after parenteral administration for investigation and imaging of the liver, thus the claimed method of cellular uptake and particle degradation would be accomplished upon administration of the modified particles. It would have been further obvious to perform the MRI diagnosis disclosed by Klaveness via T1 weighted sequences because Ranney teaches that such sequences lead to image enhancement in conjunction with gadolinium contrast agents.

Applicant argues on pages 13-17 of the Response that (i) the cited combination fails to teach all of the claim limitations, (ii) the improvement was not predictable and (iii) there are surprising and unexpected results. Applicant asserts that none of the cited references teach or suggest exploiting a specific enzymatic activity in a targeted cell in order to activate insoluble particles to a pool of water-soluble contrast agent units to record MRI images reflecting the enzymatic expression and activity. Applicant contends that degradation of “relaxometrically silent” insoluble particles to “relaxometrically active” species is necessary for activation and for obtainment of active MRI imaging probes that allow to record MRi images by use of T1-weighted sequences. This is promoted not only by naturally occurring enzymes but also by suitable enzymes expressed by

molecular biology techniques. Applicant asserts that the method allows to register MRI images relecting local expression of said specific enzyme.

This is not found to be persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., degradation by any “specific” enzyme) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims are broad and only require degradation by “effectors in the surrounding insoluble particles.”

Applicant argues that the improvement would not be predictable because both Klaveness and Grinstaff refer to uptake by organs, not cells.

This is not found persuasive. Klaveness teaches uptake by RES cells and imaging liver. Since RES cells may be located within the liver, imaging of RES cells provides imaging of liver, but the contrast agent is located within cells.

Applicant further argues that the ability to reflect expression of a specific enzyme in cells is indeed surprising and could not have been envisaged from the teaching of any of the cited references.

This is not persuasive. Applicant's allegation of unexpected results are not commensurate in scope with the claims. There is no need for any "specific" enzyme in the claims. For example, The claims are broad and only require degradation by “effectors in the surrounding insoluble particles,” as set forth above. Whether the unexpected results are the result of unexpectedly improved results or a property not

taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range. *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980). See MPEP 716.02(d).

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

LHS